



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,307	07/18/2000	Clements C. Lambeth	WEYE115226	9512

26389 7590 05/17/2005

CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC
1420 FIFTH AVENUE
SUITE 2800
SEATTLE, WA 98101-2347

EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
----------	--------------

1638

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. Box 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

RECEIVED

MAY 17 2005

TECH CENTER 1600/2900

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/618,307
Filing Date: July 18, 2000
Appellant(s): LAMBETH ET AL.

Teresa J. Wiant
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11 February 2005.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 20-31. Claim 20 is in its original form. Claims 21-31 have been previously presented.

(4) *Status of Amendments After Final*

No amendment after final has been filed.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The rejection of claims 20-31 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) *Claims Appealed*

A substantially correct copy of appealed claims 27 and 29-31 appears on pages 2-3 of the Appendix to the appellant's brief (corresponding to pages 40-41 of the Brief).

The minor errors are as follows:

In claim 27, line 1, "Currently amended" should be replaced with ---Previously presented---.

In claim 27, line 2, "consisting" should not be underlined.

In claim 27, line 5, the entire struck-through phrase should be deleted.

In claims 29-31, "New" should be replaced with ---Previously presented---.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

White, T. "Genetic parameter estimates and breeding value predictions: issues and implications in tree improvement programs." In: Dieters et al, *Tree Improvement for Sustainable Tropical Forestry* (Caloundra, Australia, 1996), pp.110-117.

Stoehr et al. "Parental environment aftereffects in germination, growth, and adaptive traits in selected white spruce families." *Canadian Journal of Forestry Research*, Vol. 28, No. 3 (1998), pp. 418-426.

Wiseloge et al. "Probability of Equal Mating in Polymix Pollinations of Loblolly Pine (*Pinus taeda* L.)" *Silvae Genetica*, Vol. 37, No. 5-6 (1988), pp. 184-187.

Rogers et al. "Unequal paternal contributions in black spruce polycross seedlots." *Heredity*, Vol. 67, No. 3, (1991), pp. 373-379.

Moran et al. "Non-random contribution of pollen in polycrosses of *Pinus radiata* D. Don." *Silvae Genetica*, Vol. 34, No. 4-5 (1985), pp. 117-121.

Strauss et al. "Limitations of molecular marker-aided selection in forest tree breeding." *Canadian Journal of Forestry Research*, Vol. 22 (1992), pp. 1050-1061.

Bridgwater, F. "Mating Designs." In: Fins et al, *Handbook of Quantitative Forest Genetics* (Dordrecht, The Netherlands, Kluwer Academic Publishers, 1992), pp. 69-95.

El-Kassaby et al. "Frequency-dependent male reproductive success in a polycross of Douglas fir." *Theoretical and Applied Genetics*, Vol. 83, No. 6-7 (1992), pp. 752-758.

Stoehr et al. "Application of a chloroplast DNA marker in seed orchard management evaluations of Douglas-fir." *Canadian Journal of Forestry Research*, Vol. 28, (1998), pp. 187-195.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

35 USC 112(1): Inadequate Written Description

Claims 20-31 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 20-29 and 31 are broadly drawn to a method of using a multitude of non-exemplified DNA markers from a multitude of taxonomically unrelated and physiologically and genetically divergent tree species including oak, pine, palm, ginkgo

Art Unit: 1638

and orange; which markers would include RFLPs, AFLPs, RAPDs, SSRs, SSR-anchored PCR-derived markers, SNPs, SSCPs, SCARs, STSs, ASAPs, SPARs and CAPs (as recited in claim 27). Claim 30 is broadly drawn to using molecular markers in a multitude of species from the single family of conifers, such as pine, spruce, fir, sequoia, hemlock, etc. The claimed methods involve the use of the molecular markers to determine pedigree and to identify elite trees for use in subsequent generations of trees, based upon their phenotypic score (see parts c and e of claim 20). Claims 20-25 and 27-31 are broadly drawn to the calculation of phenotypic score for a multitude of unrelated traits, while claim 26 is broadly drawn to the calculation of phenotypic score for at least eight particular unrelated traits. The recitation of "comprising" in the preamble of claim 20, plus the recitation of "next generation of tree breeding" in step (e) of claim 20, implies that subsequent generations of breeding and repetitions of steps (a-e) of claim 20 are contemplated.

Note: "phenotypic score" is identified on page 10 of the specification, lines 27-29, as "the objective measurement of any phenotypic trait or characteristic that is desirable in a plant breeding program". "Elite" plants are defined on page 9 of the specification, lines 27-28, as being "selected from progeny plants based on a characteristic [including]...phenotypic score". The specification further elaborates on the relationship between elite plants and trait identification, on page 13, lines 31-32, where it states that "Candidate plants are identified from the progeny plants based upon at least one objectively measured phenotypic trait".

In contrast, the specification only provides guidance for SSRs from a single coniferous species, *Pinus taeda*. No guidance is provided for the isolation or characterization of DNA from any other tree species, or for the obtention and characterization of any other type of DNA marker from any tree species. Furthermore, no guidance has been presented for the identification of any conserved sequences in the broadly claimed genus of molecular markers, which sequences are correlated with the function of identifying elite trees for their use in a breeding program, based upon their phenotypic score regarding the expression of a multitude of unrelated traits.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

See also MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991), where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Appellant's Arguments and Examiner's Response

Appellant urges that the written description rejection is improper, given the maturity of the art of tree breeding for desired traits including disease resistance at the time of filing, the maturity of the art of DNA analysis to determine pedigree in trees, the lack of a requirement for knowledge of sequence information to practice the claimed invention, and the lack of a requirement for a correlation between a trait and a particular sequence (pages 9-18 of the Brief).

Regarding the art of tree breeding for disease resistance, the Examiner maintains that none of the claims are limited to this particular trait, as stated above. Appellant has not provided any evidence that the art of tree breeding was mature for a multitude of traits including "growth rate, growth habit, chemical composition of any plant tissue, drought resistance, temperature hardiness, elevation adaptation, fecundity" as recited in claim 26.

Regarding the state of the art of pedigree analysis in trees, the Examiner maintains that the claims are not merely limited to tree breeding or to pedigree analysis. Instead, the claims are drawn to the use of pedigree analysis to identify "elite" trees, based on the determination of a phenotypic score for a particular trait. See parts c and e of claim 20, for example. Appellant has not demonstrated their possession of a representative genus of the broadly claimed species of a multitude of molecular markers from a multitude of unrelated trees useful for this purpose. Furthermore, it is unclear whether the references cited in the paragraph bridging pages 10 and 11 of the Brief

Art Unit: 1638

encompass the broadly claimed genus, or merely represent the genus of conifers as claimed in claim 30.

Regarding the alleged lack of a requirement for knowledge of marker sequences, the Examiner maintains that at least SSRs and SNPs as recited in claim 27 require such knowledge. See the Examiner's discussion of Edwards et al, Krauss et al, and Anzidei et al, previously submitted by Appellant, on page 3 of the Office action of 18 October 2004, bottom paragraph. Furthermore, Appellant's assertion that other methods, disclosed by other workers, were available for identifying SNPs (see page 16 of the Brief, first full paragraph) is not probative of Appellant's own possession of the broadly claimed invention, since *the instant specification* discloses neither SNPs nor a non-sequence-mediated method for identifying them. The Written Description Guidelines cited above require that Appellant's own specification provide an adequate written description of the broadly claimed genus.

Regarding the alleged lack of a requirement for correlating sequence with traits, the Examiner maintains that pedigree determination is but one step in the claimed process. As discussed above, open language of the claims, the recitation of multiple generations of crossing, and the definitions in the specification of "phenotypic score" and "elite plants"; support the Examiner's position that the determination of specific traits, and the correlation of such traits with particular markers, are in fact required features of steps c-e of claim 20.

35 USC 112(1): Lack of Enablement

Claims 20-31 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 20-29 and 31 are broadly drawn to a method of using a multitude of non-exemplified DNA markers from a multitude of taxonomically unrelated and physiologically and genetically divergent tree species including oak, pine, palm, ginkgo and orange; which markers would include RFLPs, AFLPs, RAPDs, SSRs, SSR-anchored PCR-derived markers, SNPs, SSCP, SCARs, STSs, ASAPs, SPARs and CAPs (as recited in claim 27); wherein said method comprises performing polymix-mediated pollination of a group of trees, utilizing said markers to determine the pedigree of progeny trees following their phenotypic scoring, and then "using the pedigree and phenotypic score to identify elite trees for use in a next generation of tree breeding" (see parts c-e of claim 20). Claims 20-25 and 27-31 are broadly drawn to the calculation of phenotypic score for a multitude of unrelated traits, while claim 26 is broadly drawn to the calculation of phenotypic score for at least eight particular unrelated traits. Claim 30 is broadly drawn to the use of the method in a multitude of species from the single family of conifers, including pine, spruce, fir, sequoia, hemlock, etc. The recitation of "comprising" in the preamble of claim 20, plus the recitation of "next generation of tree breeding" in step (e) of claim 20, implies that subsequent generations of breeding and repetitions of steps (a-e) of claim 20 are contemplated.

Note: "phenotypic score" is identified on page 10 of the specification, lines 27-29, as "the objective measurement of any phenotypic trait or characteristic that is desirable in a plant breeding program". "Elite" plants are defined on page 9 of the specification, lines 27-28, as being "selected from progeny plants based on a characteristic [including]...phenotypic score". The specification further elaborates on the relationship between elite plants and trait identification, on page 13, lines 31-32, where it states that "Candidate plants are identified from the progeny plants based upon at least one objectively measured phenotypic trait".

In contrast, the specification only provides guidance for SSRs from a single coniferous species, *Pinus taeda*. No guidance is provided for the isolation or characterization of DNA from any other tree species, or for the obtention and characterization of any other type of DNA marker from any tree species. In addition, no guidance is provided for determining actual pedigrees or phenotypes of the progenies. Only preliminary data regarding the overall relatedness of different categories of plants, such as grandparents, parents, offspring, full- and half-sibs, are provided. No guidance is provided for any further pedigree determination of individual plants. In addition, no guidance is provided for scoring the progeny for any phenotype or for selecting elite trees from the progeny.

Polymix-mediated breeding of trees for phenotypic change is unpredictable, given the lack of available knowledge regarding flower biology or pollination control in many tree species (see, e.g., White, page 113, column 1, second paragraph). In addition, environmental effects on trait expression may confound the selection of

Art Unit: 1638

desirable progeny which should possess heritable genetic components conferring the phenotypic change (see, e.g., Stoehr et al, 1998, Canadian Journal of Forest Research, Vol. 28, No. 3, pages 418-426, particularly the Abstract).

Furthermore, the use of polymix breeding may be confounded by the unequal reproductive success of many parents' pollen, so that the genetic contribution would be less diverse than planned, and which would also lead to incorrect measurements of general combining ability (see, e.g., Wiseloge et al, page 187, column 2, first full paragraph). See, e.g., Rogers et al (page 374, Table 3 and column 2; page 375, column 1; page 376, Table 6; paragraph bridging pages 376 and 377; page 377, Figure 2) who teach this phenomenon in black spruce. See also Moran et al, page 117, Abstract, who teach this phenomenon in *Pinus radiata*. Apparently only the exemplified *P. taeda* is exempt from this phenomenon (see, e.g., Wiseloge et al, page 184, column 2; page 187, column 2, top paragraph).

Equal reproductive success may be explained as follows. If the pollen from five different male parents were mixed in equal proportions, and this mixture was used to pollinate a single female parent, then the progeny of this cross should have equal proportions of genes from each of the five male parents, if equal reproductive success occurred. On the other hand, if pollen from one or more male parents germinated more quickly and/or grew more vigorously than pollen from another male parent; then this pollen would fertilize a higher proportion of eggs from the female parent. This is unequal reproductive success. The claimed method relies upon the assumption of

equal reproductive success for its determination of pedigree and its selection of elite trees for future breeding programs.

The exemplified *Pinus taeda* is unique regarding equal reproductive success of various parents' pollen, as taught by Wiseloge as stated immediately above, which equal reproductive success would be required for accurate calculations of genetic contribution and general combining ability, needed for the claimed phenotypic score and pedigree determinations. Even other pine species such as *Pinus radiata* do not share this advantageous characteristic required for accurate functioning of the claimed method, as stated immediately above. Thus, it is unpredictable that any other conifer (as claimed in claim 30), let alone any other tree species as broadly claimed in the remaining claims, would lend itself to steps c-e of claim 20.

Given the open claim language and implied repetition of the claimed process as stated above, the claimed method involves the measurement of particular phenotypic traits in each generation of progeny plants. With each subsequent generation of crossing, the identification of a phenotypic score for a particular trait, coupled with identifying the pedigree of a progeny plant exhibiting that particular trait, would necessarily result in the use of molecular markers to predict the ability of particular parents to transmit particular desired traits to future generations of progeny. In other words, following multiple generations of crossing, individual traits would in fact be correlated with, or linked to, particular markers. The use of molecular markers to predict the ability of plants to confer a particular trait to their progeny is termed "molecular marker-mediated selection."

However, such molecular marker-mediated selection in tree breeding, particularly in open-pollinated schemes such as polymix breeding, is unpredictable. See, e.g., Strauss et al, page 1050, Abstract, who teach that molecular markers are of limited availability and of high cost, are restricted to particular genetic backgrounds, and that many traits of interest to tree breeders are highly environmentally influenced, which would interfere with selection of phenotypes to which markers could be reliably assigned. Strauss et al also teach that molecular markers are more useful in controlled hybrid breeding schemes or full-sib families (see, e.g., Abstract), rather than the instantly claimed polymix breeding where mixtures of several parents' pollen are utilized in a half-sib scheme. In addition, linkage equilibrium will confound trait-marker associations (see, e.g., page 1052, column 2, penultimate paragraph; page 1053, column 1, second full paragraph). See also page 1053, column 2; paragraph bridging pages 1053 and 1054; page 1054, column 2, third and fourth full paragraphs; paragraph bridging pages 1054 and 1055.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate a multitude of non-exemplified markers from the exemplified tree species or from a multitude of non-exemplified tree species, to develop and evaluate progeny phenotype scoring systems in a multitude of tree species and for a multitude of phenotypes, to utilize polymix breeding to obtain selectable phenotypic change and identify "elite trees" in a multitude of exemplified or non-exemplified tree species for a multitude of non-exemplified traits, or to utilize a multitude of exemplified or non-

exemplified DNA markers to identify the pedigree of a multitude of exemplified or non-exemplified progeny from a multitude of exemplified or non-exemplified tree species and polymix-generated progeny.

Appellant's Arguments and Examiner's Response

Appellant urges that the enablement rejection is improper, given the availability of molecular markers in a wide range of tree species as demonstrated by publications previously cited and supplied by Appellant, the conservation of chloroplast sequences in different pine and conifer species, the incorrect interpretation by the Examiner of the teachings of references previously cited by Appellant to support his position, the lack of a requirement for undue experimentation in determining phenotypic score or selecting an elite breeding group as demonstrated in the specification, the failure of the references originally cited by the Examiner to support his position, and the lack of uniqueness of the single exemplified species of *Pinus taeda* chloroplast SSR markers (Brief, pages 19-34).

Regarding the availability of other molecular markers from other tree species, as demonstrated by the publications of other workers (Brief, page 22, bottom paragraph), the Examiner maintains that the instant specification only demonstrates the identification of chloroplast SSR markers from a single pine species.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Furthermore, the mere disclosure of molecular markers from tree species is not the sole issue. Rather, the unpredictability of utilizing such markers, even if they were successfully isolated, in the claimed method of correlation with a phenotypic score, pedigree determination, and identification of elite trees for future breeding generations, is the issue. The Examiner has demonstrated that the claims read on such a method which requires the correlation of molecular markers with the ability to predict the successful transmission of particular traits to progeny trees, wherein the references submitted by the Examiner clearly demonstrate such unpredictability.

Regarding the alleged conservation of chloroplast DNA sequences across conifers such as pine, the Examiner maintains that only claim 30 is even limited to conifer, while all of the other claims are broadly drawn to any tree species. Appellant has not demonstrated that chloroplast DNA sequences are conserved in genetically divergent tree species such as oak, apple, orange, Saguaro cactus, date palm, ginkgo, etc. Furthermore, none of the claims are limited to chloroplast DNA sequences for use as markers.

Regarding the Examiner's interpretation of the references previously submitted by Appellant, the Examiner maintains that such references contain admissions of unpredictability in the identification and use of molecular markers from a variety of tree species as broadly claimed, as stated previously, and as summarized by Appellant on pages 23-28 of the Brief. Even if such references also contain optimistic suggestions about the future of their disclosed techniques, or disclose some limited instances of success; the Examiner maintains that the references demonstrate the unpredictability

inherent in utilizing exemplified or non-exemplified molecular markers from exemplified or non-exemplified tree species in order to select elite trees for future breeding, as claimed (see parts c and e of claim 20). Thus, Staub et al is eminently applicable in its teachings of the unpredictability inherent in marker-assisted selection, since the claims and the specification teach just such a process, as discussed above; contrary to Appellant's assertions on pages 27-28 of the Brief.

At most, the references demonstrate success when utilizing molecular markers for determining paternity or pedigree, i.e., step (d) of claim 20. See Krauss et al, who only demonstrate successful *pedigree determination* in a single highly outcrossing species (see page 544, Conclusion, as indicated by Appellant on page 25 of the Brief, top paragraph; see also page 533, bottom paragraph, as previously cited by the Examiner, where it is taught that "The species is completely outcrossing"). In contrast, the claims read on a multitude of tree species, including highly inbreeding species with low or zero levels of outcrossing. Furthermore, the claims read on additional phenotypic scoring and elite tree identification steps, as stated above, which were not taught by Krauss et al.

Appellant's single example, of a single marker system from a single pine species, is insufficient to rebut the evidence of unpredictability when other marker systems and other tree species, encompassed by the broad claims, are employed.

Furthermore, the references cited by Appellant were largely limited to the genus of conifers, as claimed in claim 30, rather than encompassing any and all unrelated trees, as broadly claimed in claim 20 and all other dependents. For example, Anzidei et

al teach limited success using chloroplast SSR markers (the same type of markers utilized by Appellant) in silver fir, a conifer (see page 3 of the reference, as indicated on page 23 of the Brief, top paragraph).

Regarding Appellant's inability to find particular teachings in Nicese et al (Brief, page 24), the Examiner hereby directs Appellant to the following portions of that reference where those teachings are found. The influence of environmental conditions on marker data is taught on page 202, column 1, bottom paragraph, first sentence: "...questions have been raised about the reliability of RAPD data due to their variable nature under different experimental conditions". The teachings of "the requirement for close relatedness" and "the requirement of larger numbers of generations of crossing and molecular markers" may be found on page 204, paragraph bridging the columns, particular sentences excerpted below, emphasis added:

However, it was not possible to compare the genetic similarity values estimated with the Nei & Li index with the coefficients of ancestry... due to three main reasons. One, that the available pedigree consists of a maximum of *just two generations*. Second, the French and Canadian cultivars *are probably related* since the genetic base of the Californian cultivars has been enriched with introductions from France. Third... *a higher number of markers will probably be needed* to obtain a dendrogram that accurately reflects the similarity matrix...

Regarding the actual disclosure on page 21 of the specification, lines 14-20 (see page 27 of the Brief, top paragraph), the cited portion merely provides general suggestions regarding which traits to measure, and at what developmental stage to measure them. The specification does not provide detailed information on actual measurements, or even any instruction on which aspect of disease resistance, insect resistance, "general health and deformities", etc. to measure. Should disease

Art Unit: 1638

resistance be measured in terms of frequency and/or severity of leaf or root lesions, degree of wilting of the entire plant, degree of reduction in fruit set, etc? How should "general health and deformities" be measured?

Furthermore, there was no demonstration in the specification of trait measurement for any of the progeny trees for which pedigree information was allegedly obtained, as claimed in part c of claim 20; and no demonstration of any identification of elite trees to be used in further generations of breeding, as claimed in part e of claim 20. The Examiner's scientific reasoning and previously cited publications, relied upon to support his position of unpredictability, are not overcome by the specification's teaching of only one type of molecular marker from one plant species for carrying out step d of claim 20; and the specification's lack of conclusive teachings of any successful results of practicing the entire claimed method, particularly steps c and e, for any broadly claimed tree species and any broadly claimed marker system.

Regarding the references originally cited by the Examiner to support his position, and Appellant's rebuttal thereof on pages 29-31 of the Brief, the Examiner maintains that Stoeher et al is applicable because the claims are indeed drawn to a method of marker-assisted phenotypic selection, as stated above. Furthermore, the open pollination method taught by White is analogous to the polymix-mediated breeding method taught by Appellant, since single male and female parents are not used. Regarding Wiseloge et al, the Examiner maintains that Appellant's mere assertions of the desirability of their method are insufficient to rebut the teachings of the cited publication regarding the unpredictability inherent in polymix breeding.

Regarding the unique qualities of the exemplified species *Pinus taeda*, Appellant is directed to page 6 of the Office action of 20 January 2003, top paragraph, where it is taught that this species is unique in its equal reproductive success of many parents' pollen, as taught by Wiselogle et al. Such equal reproductive success would be critical for the accurate determination of pedigree as claimed in step d of claim 20. Since Appellant utilized the same species as the single species which was taught by Wiselogle et al to be uniquely suited to the claimed method, Appellant's assertions that any other species would work are not probative.

35 USC 103: Obviousness

Claims 20-31 on appeal stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bridgwater in view of El-Kassaby et al, further in view of Stoeher et al (1998, Canadian Journal of Forestry Research, Vol. 28, pages 187-195).

Claims 20-29 and 31 are broadly drawn to a method of breeding any tree species, comprising utilizing polymix pollination of each pollen source individually, scoring progeny trees for a particular phenotype of interest, determining the pedigree of the progeny via DNA analysis, and selecting elite trees for further breeding. Claim 30 specifies that the trees involved are conifers. Claim 26 specifies that particular traits may include disease resistance, and general combining ability-influenced traits such as growth rate and fecundity. Claim 27 specifies various types of molecular markers including DNA markers.

Bridgwater teaches the advantages of polymix-mediated tree breeding regarding selection for particular phenotypes such as resistance to rust disease, general

Art Unit: 1638

combining ability, and gains in additive genetic variation; wherein one type of polymix scheme is complete nesting involving the use of all pollen parents as females (analogous to the polymix breeding scheme utilized by Appellant); and wherein the scheme generally costs less than other breeding schemes such as diallel crossing (see, e.g., pages 74-76). In particular, Bridgwater teaches the importance of considering “(2) the use of genetic testing [i.e. pedigree determination as recited in step (d) of claim 20], (3) the management of co-ancestry, and (4) the choice of mating design” (see page 69, bottom paragraph).

Bridgwater does not teach the use of molecular markers to determine pedigree.

El-Kassaby et al teach the use of molecular markers such as isozymes to determine the pedigree of progeny from a polymix cross of Douglas fir trees (see, e.g., page 753, column 1, bottom two paragraphs; column 2, Table 1 and first two full paragraphs; paragraph bridging pages 754 and 755; page 755; page 756, Table 6 and column 2, second and third full paragraphs).

Stoehr et al teach the use of DNA markers to identify pedigree in Douglas fir, wherein the technique has many advantages including increased accuracy and resolution over other markers such as isozymes (see, e.g., page 187, Abstract; page 188, column 1, second full paragraph; page 193, column 1, first full paragraph). In particular, on page 188, column 1, second full paragraph, Stoehr et al teach the superiority of DNA markers over isozymes in the “direct determination of male parentage” (i.e., pedigree as claimed in part (d) of claim 20).

It would have been obvious to one of ordinary skill in the art to utilize the method of polymix tree breeding taught by Bridgwater, and to modify that method by utilizing the pedigree analysis step in the Douglas fir polymix breeding program taught by El-Kassaby et al, as suggested by Bridgwater; and to further modify that method by utilizing the DNA marker taught by Stoehr et al, given the teachings of the superiority of DNA markers in pedigree determination as taught by Stoehr et al; given the recognition by those of ordinary skill in the art that each would have continued to function in its known and expected manner.

Appellant's Arguments and Examiner's Response

Appellant urges that the obviousness rejection is improper, given the failure of the primary reference to teach all of the claimed elements, the failure of the secondary or tertiary references to teach all of the claimed elements, and the lack of motivation to combine the teachings of the secondary and tertiary references (Brief, pages 35-38).

In response to Appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to Appellant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the references clearly provide such motivation, as stated above and below.

Regarding the primary reference, the Examiner maintains that Bridgwater clearly teaches the use of a polymix breeding scheme in tree breeding including its advantages, and clearly suggests the use of pedigree determination in tree breeding programs, i.e. step d of claim 20, as stated above and previously. Regarding step e of claim 20, it is noted that the identification of "elite trees for use in a next generation of tree breeding" is being interpreted as a general intended use. Furthermore, the instant specification provides no detailed steps regarding any aspect of step e of claim 20, which detailed steps might possibly distinguish the instant invention from the prior art.

Regarding the secondary and tertiary references, the Examiner maintains that El-Kassaby et al clearly teach the use of molecular markers to determine paternity (i.e., pedigree determination of step d of claim 20) in a polymix of the conifer Douglas fir, as stated above and previously. Furthermore, Stoehr et al clearly teach the superiority of chloroplast DNA markers for pedigree determination in Douglas fir, as stated above and previously. Given the teaching by Bridgwater of the desirability of polymix breeding and pedigree determination, the teaching by El-Kassaby et al of the desirability of combining pedigree determination with polymix breeding in Douglas fir, and the teaching by Stoehr et al of the superiority of DNA markers in determining pedigree in Douglas fir, one of

Art Unit: 1638

ordinary skill in the art would have been motivated to combine the teachings of the prior art in order to obtain the claimed invention.

Furthermore, it is noted that Appellant's only evidence of unexpected results relies upon the use of a single type of chloroplast DNA marker in a single pine species, to perform steps a, b and d of claim 20. In contrast, the claims are broadly drawn to any tree species, any molecular marker, and phenotypic score for any trait, in order to identify elite trees for use in a future generation of tree breeding. Thus, the evidence of unexpected results for steps a, b and d of claim 20 is not commensurate with the claim scope. It is noted that no evidence of success has been provided for steps c and e of claim 20.

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

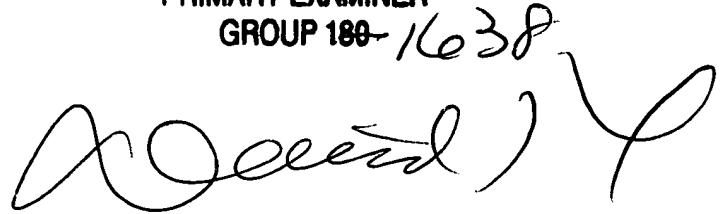
Art Unit: 1638

Conclusion

Accordingly, it is considered that Appellant has failed to demonstrate that the Examiner's positions were in error. Thus, it is respectfully submitted that the Examiner's rejections of claims 20-31 on appeal under 35 USC 112, first paragraph and 35 USC 103 be MAINTAINED.

Respectfully submitted,

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", with a large, stylized flourish extending from the end.A handwritten signature in black ink, appearing to read "Amy Nelson", written in a cursive style.

Amy J. Nelson, SPE
Art Unit 1638
Conferee

A handwritten signature in black ink, appearing to read "Bruce Campell", written in a cursive style.

Bruce Campell, SPE
Art Unit 1654
Conferee

Christensen, O'Connor, Johnson & Kindness PLLC
1420 Fifth Avenue, Suite 2800
Seattle WA 98101